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Multidisciplinary effort codifies recommendations into a series of pathways

New impetus to recognize and manage peripheral artery disease

Peripheral arterial disease (PAD) affects millions of Americans, but the multiple clinical syndromes are often overlooked by practitioners who may lack specific vascular training to help them establish effective diagnostic and management strategies for the condition. This is unfortunate because inaction -- particularly in certain high-risk groups -- can often lead to considerable morbidity, mortality, and cost. Undiagnosed PAD is associated with adverse limb and cardiovascular events that could have been prevented with proper early management.

Part of the problem may relate to the fact that "PAD" is a broad clinical term that includes diverse diseases of the arteries that supply blood to the lower limbs, the kidneys, and the intestines (and all other "non-coronary" arterial beds). Consequently, the establishment of best practices for these conditions has traditionally been a complex multi-disciplinary effort, requiring the expertise of specialists in interventional radiology, vascular medicine and cardiology, vascular surgery, and other disciplines.

However, in an exceptional coordination of effort, leading practitioners from each of these disciplines have collaborated to create the first set of comprehensive clinical care guidelines for the management of individuals with PAD.

Released by the American College of Cardiology and the American Heart Association, in partnership with the Society for Vascular Surgery, Society for Vascular Medicine and Biology, Society for Interventional Radiology, and Society for Cardiovascular Angiography and Interventions, the guidelines are intended for use by the many different types of practitioners who care for patients with PAD. However, the lead authors of the guidelines are particularly hopeful that PCPs will benefit from the information as they are best positioned to identify PAD at its earliest stages. The care pathways outlined in the guideline could help improve the natural history of the disease, improving quality of life and preventing heart attack and stroke, aneurysm rupture, and amputation.

Urging a more proactive stance

The guidelines are thorough and extensive, covering the chief diagnostic and treatment strategies for PAD, and classifying the evidence to support the myriad recommendations. Further, the document includes an abundance of data tables and care algorithms to guide care by the treating clinician through

Inside This Month...

- **New, quick assessment tool is leaving many physicians stunned.** Why? Because they're finding out just how many of their patients have low-health literacy, a problem that is much more common than most practitioners believe, affecting as much as half the population. Studies show that low health literacy is responsible for poorer outcomes and substantial costs. To address the issue, researchers have developed and validated a new tool that can assess health literacy in as little as three minutes Page 6
- **Two health care giants join forces to offer groundbreaking Medicare program.** The seventh of eight pioneering Medicare Health Support programs is now underway with the launch of Green Ribbon Health, a Tampa, FL-based company formed by Pfizer and Humana in an attempt to take advantage of the depth of DM experience that each has to offer in caring for a highly complex Medicare population Page 8
- **Time for a dramatic shift in focus toward chronic care.** That's the contention of a critical new report that cites multiple failings in the health care infrastructure that are jeopardizing quality and progress on a number of fronts, but particularly with regards to diabetes. Using a "fairly modest" set of assumptions, the lead author states that diabetes is on track to be the nation's number one killer within 20 years unless something is done to stem the epidemic of obesity Page 10

all stages of the disease. (www.acc.org/clinical/guidelines/pad/index.pdf.) However, it is useful here to review the chief clinical clues that should trigger clinicians to consider a diagnosis of PAD, and to discuss why the authors of the guidelines have concluded that practitioners need to take a much more proactive approach toward identifying and managing the disease.

"It has long been known that all clinical PAD syndromes are associated with an elevated risk of heart attack and stroke. In fact, the traditional, non-aggressive approach to establishing the PAD diagnosis has been challenged for five or ten years. Each contributing vascular society, based on excel-

lent epidemiologic and clinical trial data, has been eager to assure that effective diagnostic pathways could be linked to effective therapies. But, we have all been previously challenged to identify a common platform in which we could evaluate the evidence base to create consensus-driven diagnostic and therapeutic recommendations to improve national vascular care standards," explains **Alan T. Hirsch, MD, FACC, FAHA**, chairman of the guideline writing committee, and both associate professor of epidemiology at the University of Minnesota and director of the vascular medicine program at the Minneapolis Heart Institute at Abbott Northwestern Hospital in Minneapolis. "So, from this perspective, most of these recommendations are not revolutionary; they are just novel because we have codified them into a series of cogent pathways."

Populations at risk for lower-extremity PAD

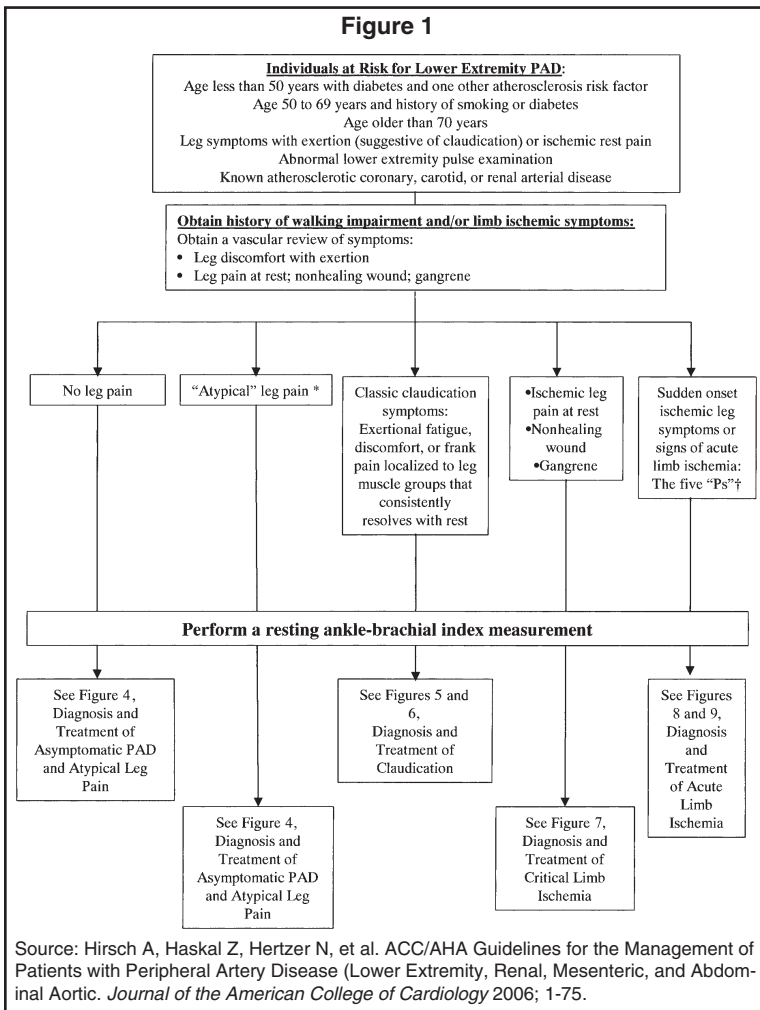
The guidelines first address lower extremity PAD, the most common form of the disease. It affects a large proportion of the population, so the authors urge clinicians to be particularly vigilant in establishing the lower extremity PAD diagnosis in groups known to be at highest risk. (See Figure 1.) PAD is not a disease that only

Figure 2: Key Components of the Vascular Review of Systems and Family History

- Any exertional limitation of the lower extremity muscles or any history of walking impairment. The characteristics of this limitation may be described as fatigue, aching, numbness, or pain. The primary site(s) of discomfort in the buttock, thigh, calf, or foot should be recorded, along with the relation of such discomfort to rest or exertion.
- Any poorly healing or nonhealing wounds of the legs or feet.
- Any pain at rest localized to the lower leg or foot and its association with the upright or recumbent positions.
- Postprandial abdominal pain that reproducibly is provoked by eating and is associated with weight loss.
- Family history of a first-degree relative with an abdominal aortic aneurysm.

Source: Hirsch A, Haskal Z, Hertzner N, et al. ACC/AHA Guidelines for the Management of Patients with Peripheral Artery Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic). *Journal of the American College of Cardiology* 2006; 1-75.

Figure 1



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affects the elderly. Thus, the guideline suggests that active diagnostic efforts be applied in younger patients less than 50 years old, including diabetics who have at least one additional atherosclerotic risk factor. In patients over the age of 50 years, individuals with a history of smoking or diabetes are known to also be at high risk, as are patients who exhibit the classic symptoms of leg pain/discomfort or claudication. Other factors that identify a high risk of PAD include an abnormal lower extremity pulse examination, age over 70, or a known atherosclerotic coronary, carotid, or renal artery.¹ Hirsch emphasizes that a history of smoking is a particularly strong risk factor for lower extremity PAD; more than 80% of patients with this form of the disease are current or former smokers.

Given that patients do not always voluntarily offer information about these signs or symptoms during increasingly busy office visits, Hirsch emphasizes that practitioners need to take the diagnostic initiative. To simplify this process, the guideline authors developed what they refer to as a “vascular review of symptoms”—a short checklist of items that can quickly provide clues to any relevant signs or symptoms that lower extremity, renal, mesenteric, or aortic aneurysmal PAD may be present. (See Figure 2 on page 2.)

“We ask physicians to be proactive and ask about any first-order relatives with aneurysmal disease, as this identifies a high risk cohort in which an aortic ultrasound study is indicated. Similarly, we believe that exertional leg discomfort is as potentially important a hallmark ‘ischemic symptom’ as chest pain. The symptoms may seem common, but identification of claudication is no less important than identifying angina as a cause of chest pain. This parallel focus should not shock clinicians, as the clinical impact of establishing the PAD diagnosis is no less important than CAD.” notes Hirsch. “But the reality is that individuals with leg discomfort don’t volunteer this information to their physicians in a society where leg pain is relatively common. Thus, the guideline can serve as

a tool to help clinicians use their common sense to identify atherosclerotic disease, and we ask patients and clinicians to slow down and talk to each other.”

Figure 3: Typical Noninvasive Vascular Laboratory Tests for Lower Extremity PAD Patients by Clinical Presentation

Clinical Presentation	Noninvasive Vascular Test
Asymptomatic lower extremity PAD	ABI
Claudication	ABI, PVR, or segmental pressures Duplex ultrasound Exercise test with ABI to assess functional status
Possible pseudo-claudication	Exercise test with ABI
Postoperative vein graft follow-up	Duplex ultrasound
Femoral pseudoaneurysm; iliac or popliteal aneurysm	Duplex ultrasound
Suspected aortic aneurysm; serial AAA follow-up	Abdominal ultrasound, CTA, or MRA
Candidate for revascularization	Duplex ultrasound, MRA, or CTA

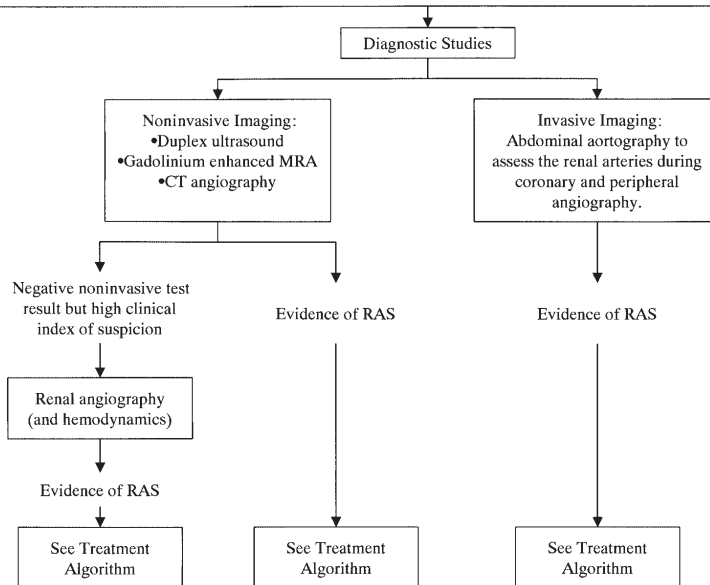
Adapted from *Primary Cardiology*, 2nd ed., Braunwald E, Goldman L, eds., “Recognition and management of peripheral arterial disease,” Hirsch AT, 659-71, Philadelphia, PA: WB Saunders, Copyright 2003, with permission from Elsevier (30a).

AAA = abdominal aortic aneurysm; ABI = ankle-brachial index; CTA = computed tomographic angiography; MRA = magnetic resonance angiography; PAD = peripheral arterial disease.

Source: Hirsch A, Haskal Z, Hertzner N, et al. ACC/AHA Guidelines for the Management of Patients with Peripheral Artery Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic). *Journal of the American College of Cardiology* 2006; 1-75.

Figure 4

- Clinical Clues to the Diagnosis of Renal Artery Stenosis**
1. Onset of hypertension before the age of 30 years or severe hypertension after the age of 55.* (Class I; LOE B)
 2. Accelerated, resistant, or malignant hypertension.* (Class I; LOE C)
 3. Development of new azotemia or worsening renal function after administration of an ACE inhibitor or ARB agent. (Class I; LOE B)
 4. Unexplained atrophic kidney or size discrepancy between kidneys of greater than 1.5 cm.† (Class I; LOE B)
 5. Sudden, unexplained pulmonary edema. (Class I; LOE B)
 6. Unexplained renal dysfunction, including individuals starting renal replacement therapy. (Class IIa; LOE B)
 7. Multi-vessel coronary artery disease. (Class IIb; LOE B)
 8. Unexplained congestive heart failure. (Class IIb; LOE C)
 9. Refractory angina. (Class IIb; LOE C)



Source: Hirsch A, Haskal Z, Hertzner N, et al. ACC/AHA Guidelines for the Management of Patients with Peripheral Artery Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic). *Journal of the American College of Cardiology* 2006; 1-75.

Diagnostic alternatives

In addition to stressing the importance of early PAD detection, the guideline also focuses on effective deployment of the many possible diagnostic testing procedures. Hirsch emphasizes that easy, cost-effective tests can unmask the large burden of disease. "For most individuals, during the lifetime of their PAD, all they will ever need is an ankle-brachial index (ABI), a very inexpensive and reproducible test," he says. "It defines the presence of the disease and offers a quantitative measure of severity."

Unfortunately, the ABI is not as readily available as it should be, according to Hirsch, but he is hopeful that the new guideline will influence health care organizations and payers to make positive changes in this regard. "The ABI should not remain available only by referral to vascular labs, creating a major potential barrier to its effective use, but should be available in almost every primary care office; the ABI is equivalent to an EKG," stresses Hirsch. "But right now obtaining an ABI often requires the patient to speak with his physician, sometimes two or three times, then make an appointment with a vascular lab, and then make another appointment with the physician to obtain the results. As well, current standards for reimbursement are not based on the evidence base that defines the ideal use of the test, and thus the ABI is often not reimbursed."

Some patients will need further diagnostic testing to determine an ideal therapeutic plan, but this generally applies to a small subset of patients with severe symptoms. (See Figure 3 on page 3.) "Individuals who don't have limb ischemic symptoms don't need expensive imaging tests and shouldn't be asking for them," notes Hirsch, referring to one of the class III recommendations in the guideline. "There is no reason to be spending \$2,000 on scans that won't impact outcomes. The guideline authors intended to serve as responsible guardians of the science base, as well as to provide a responsible approach to strategies of deploying tests."

An opportunity for effective intervention

Once lower extremity PAD has been identified, the treatment alternatives are well-documented and include therapies to achieve systemic risk reduction for heart attack, stroke, and death, and limb-specific treatments to improve walking and prevent amputation. What has been missing in previous documents, according to Hirsch, has been guidance on how to detect the disease. And this is where he is hopeful that the guideline will make the greatest impact.

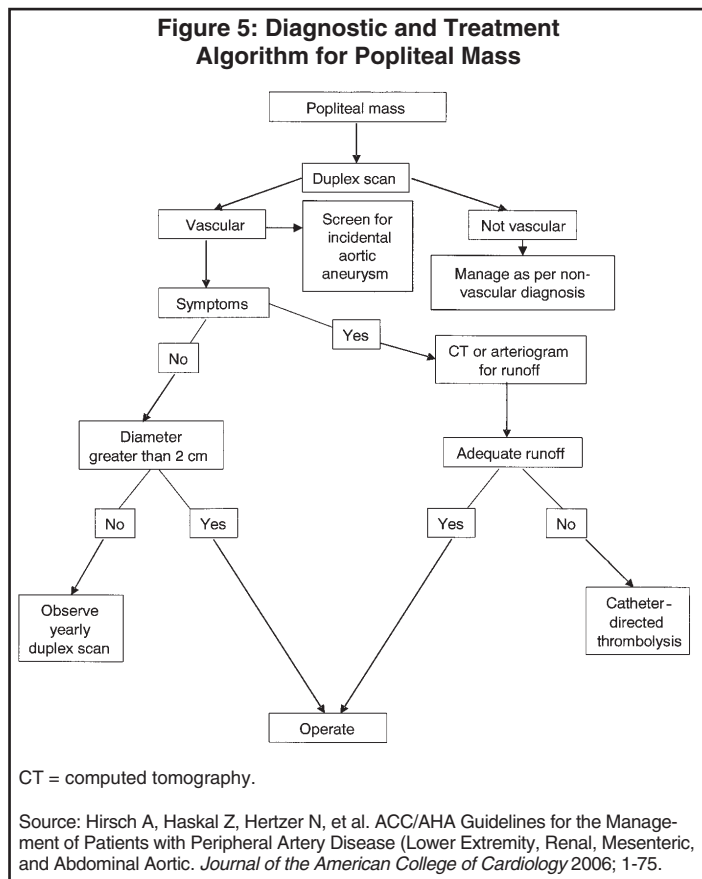
"PAD reflects one of those obvious manifestations of atherosclerosis that could be diagnosed with ease, via a simple medical history, or palpated

with your fingers, or detected with an inexpensive ultrasound device," Hirsch comments. "We should have less hubris, as a physician's actions or inactions can have a major positive or negative clinical impact for an individual with PAD within three to five years. The ability of a physician to define any evidence of PAD -- even if relatively asymptomatic -- places into the hands of the patient and the physician the freedom to act to preserve health."

Renal artery stenosis

Renal artery stenosis (RAS) is not as common as lower-extremity PAD, but it is especially important to look for this condition in patients who have lower-extremity PAD or evidence of atherosclerosis in other arteries.¹ Furthermore, authors of the new guideline stress the importance of recognizing clinical signs that RAS may be present. (See Figure 4 on page 3.) These include the onset of hypertension in an unusually young individual, severe hypertension in older patients, worsening kidney function following the administration of an ACE inhibitor or ARB, and unexplained CHF or sudden, unexplained pulmonary edema. Other clues include one kidney that is at least 1.5 centimeters smaller than the other one, refractory angina, and extensive CAD.

In developing the guideline, the authors categorized each clue according to the evidence-base sup-



porting its inclusion, and they stress that physicians should carefully consider this factor when determining how to proceed. However, in many cases the best course of action will be to have the patient undergo a non-invasive screening procedure -- such as magnetic resonance angiography (MRA), computed tomographic angiography (CTA), or renal vascular ultrasound -- to confirm or rule out the presence of RAS.

Alternative treatments for a confirmed diagnosis of RAS include medical therapy to control the resulting hypertension, surgical repair, or catheter-directed therapies such as balloon angioplasty and stent placement. However, the PCP's chief responsibility is to diagnose the condition and make referrals, when appropriate.

"Our intent was not to recommend one form of treatment over another, but rather to have clinicians understand when they should look for these, understand what the indications for therapy are, and refer to a vascular specialist," emphasizes **Ziv Haskal**, MD, FAHA, FSIR, co-chairman of the guideline writing committee and director of vascular and interventional radiology at New York Presbyterian Hospital. "An undiagnosed condition is an opportunity for all clinicians who see the patient."

Abdominal aortic aneurysms

Abdominal aortic aneurysms (AAAs) -- another important form of PAD covered extensively in the guideline -- are most common in older men, affecting 12.5% of men aged 75 to 84 years old. However, clinicians should be particularly vigilant in screening for AAAs in male smokers, and anyone with a family history of the condition. Additionally, discovery of an aneurysm in a lower extremity should definitely trigger further investigation, according to **Norman R. Hertzner**, MD, FACS, a co-chairman of the guideline writing committee and emeritus chairman of the Department of Vascular Surgery at the Cleveland Clinic Foundation in Cleveland, OH. "If one finds a popliteal aneurysm, for example, there is a 40% to 60% chance that the same patient will have an aortic aneurysm of some size," explains Hertzner. "Any of these clues should lead to an ultrasound exam."

In most cases, ultrasonography is a very precise screening test for AAAs because 95% of them are located at or below the renal arteries. In a small percentage of cases, a CT or MR scan may be needed to confirm a diagnosis, but Hertzner emphasizes that AAAs are not easily misdiagnosed. In fact, he stresses, many AAAs are easily detected via a thorough physical exam. "I would like to see more patients who actually get on the examining table, lie on their back, and have their doctor examine their abdomen, but I am not sure how often that happens," he says.

New studies largely conducted in the UK and in the VA system suggest that aneurysms that are smaller than 5.5 centimeters do not necessarily require immediate repair or treatment. However, Hertzner stresses that it is important to regularly monitor these AAAs for any signs of enlargement because the mortality rate for a ruptured aneurysm is well over 50%. "Once a patient ruptures an aneurysm, all sorts of bad things start to happen: shock, myocardial infarction, and kidney failure. Even if the individual has a successful operation to repair the ruptured aneurysm, he or she may still die three weeks later in the ICU. That is quite a common scenario," says Hertzner. "It is a very grim situation, despite whatever you do, so a 5% or less mortality rate for open repair, or a 2% or less mortality rate for endografting starts to look awfully good."

While AAAs are much more common in men than in women, studies have shown that aneurysm rupture is more likely to occur in women with the condition, so Hertzner urges clinicians to be alert to the presence of AAAs in women -- particularly those with a family history of the condition.

An opportunity to improve CVD care

It is important to note that an estimated 5% of patients with AAAs also have a popliteal aneurysm -- a condition which may be asymptomatic but is nonetheless important to diagnose because large popliteal aneurysms (over 2 centimeters) can effectively cut off circulation to the lower leg, raising the risk for amputation. Most popliteal aneurysms can be diagnosed through an attentive physical examination, and when treatment is indicated, they are typically repaired through the use of a bypass graft, although there are some other treatment approaches. (See Figure 5 on page 4.)

The association between AAAs and popliteal aneurysms is more evidence of the larger concept that all the different forms of PAD are a result of the same process that causes cardiac disease.

"The guidelines represent an interdisciplinary effort across all related specialties in the hope of improving all cardiovascular disease," emphasizes Haskal. "There is the opportunity to reduce the risks for PAD, to treat it, and identify by diagnosis the increased risk for other conditions, such as cardiac disease. And overall CVD morbidity and mortality can be reduced by identifying and possibly intervening medically, surgically, or endovascularly in these conditions."

Reference

1. Hirsch A, Haskal Z, Hertzner N, et al. ACC/AHA Guidelines for the Management of Patients with Peripheral Artery Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic). *Journal of the American College of Cardiology* 2006; 1-75. ♦

Health literacy: The most important vital sign?

The inability to understand medical information -- or poor health literacy -- is a much bigger problem than most practitioners realize. The Institute of Medicine and the National Adult Literacy Survey suggest that 40% to 50% of the U.S. population falls into this category. And the results of this deficit have a deleterious impact on all types of DM: medication errors are rampant, patients show up unprepared to undergo important medical tests, and critical self-management skills are not acquired. Further, researchers have documented that people with low health literacy have more hospital admissions and higher health care costs.¹ In fact, costs associated with low health history are estimated to be between \$58 and \$73 billion annually.

Addressing this problem is a two-step process, according to **Barry Weiss**, MD, a professor of family and community medicine at the University of Arizona College of Medicine. Physicians and other health care practitioners must come to appreciate that poor health literacy is a major problem -- and that it is most definitely impacting their own practice. Then, once this awareness has been achieved, they need to be armed with tools and strategies that can help them overcome literacy-related problems.

To that end, Weiss and a team of researchers at the University of Arizona worked in collaboration with colleagues at the University of North Carolina to develop and validate a new tool that can quickly determine whether patients can understand and act upon important health information. While researchers are continuing to study and refine the tool, it is already available so that health care organizations and individual practitioners can begin to address this problem.

Other tools fall short

While there are other tools available to measure health literacy -- most notably the Test of Functional Health Literacy in Adults or TOFHLA, and the Rapid Assessment of Adult Literacy in Medicine or REALM -- Weiss notes that none meet the critical criteria of being quick, easy to implement, and available in both English and Spanish. "The TOFHLA takes eight to ten minutes or even longer [to administer], and the REALM, which is doable in a couple of minutes, is not available in Spanish," explains Weiss, noting that because REALM is a word recognition list, it does not work effectively when translated into Spanish. "In Spanish every letter is always pronounced exactly

the same, no matter what word it is in, so all you have to do is know how to sound out words in Spanish, and you can read a multi-syllable word and pronounce it correctly, which tells you nothing about a patient's ability to read, understand, and recognize words."

To get around these barriers, Weiss and his team devised a series of health-related scenarios involving written instructions, and then tested how well people were able to understand and respond to the information. (See **Figure 1**.) In selecting test scenarios, researchers were cognizant of research showing the importance of understanding mathematical concepts as well as literacy when dealing with health information.

The process went through several refinements, but ultimately investigators found that an instrument asking patients to answer six questions about a simple ice cream nutritional label was most effective at assessing health literacy. (See **Figure 2 on page 7**.) When tested on 250 English-speaking patients and 250 Spanish-speaking patients, results from this instrument strongly correlated with results from the TOFHLA, although the English version of the label proved most effective.¹

A critical piece of information

When considering a name for the instrument, investigators determined that "The Newest Vital Sign" or NVS was most appropriate. "What we envisioned was a short, quick way for physicians to assess whether patients understand medical information," explains Weiss, noting that physicians can do the test or they can have a nurse do the assessment while they are collecting other vital sign infor-

Figure 1: Reliability and Validity of English and Spanish Candidate Scenarios and Total Test

Scenario	Number of Items	Reliability: Cronbach α	Validity*: Pearson r
English			
1. Prescription for headache medication	3	0.23	0.43
2. Consent form for angiography	4	0.40	0.51
3. Self-care instructions for heart failure	5	0.38	0.20
4. Nutrition label from ice cream†	6	0.76	0.59
5. Instructions for tapering prednisone	3	0.66	0.35
Total	21	0.78	0.64
Spanish			
1. Prescription for headache medication	3	0.37	0.38
2. Consent form for angiography	4	0.37	0.55
3. Self-care instructions for heart failure	5	0.33	-0.01
4. Nutrition label from ice cream†	6	0.69	0.49
5. Instructions for tapering prednisone	3	0.39	0.37
Total	21	0.69	0.59

* Correlation of scenario score and score on criterion (ie, Test of Functional Health Literacy in Adults, Spanish Version).

† This scenario (nutrition label) was selected as the single best scenario, and is the content of the Newest Vital Sign -- Spanish.

Source: Weiss B, Mays M, Martz W, et al. Quick Assessment of Literacy in Primary Care: The Newest Vital Sign, *Annals of Family Medicine* 2005; 3:514-522.

mation. "This is a critical piece of information about a patient. A lot of people say that smoking status is a vital sign, so at each patient visit you write down the patient's BP, pulse, weight, and their smoking status, and here we believe is another vital sign. Whether or not the patient can understand the information that is being given is more important than all the other vital signs."

Weiss acknowledges that identifying patients with low health literacy is only part of the problem. Practitioners must then be able to effectively communicate with these patients for the information to make a difference -- and that is, apparently, a tall order. "If you ask a hundred physicians if they are good at communicating, they will say yes, they are good at communicating with patients. But if you watch physicians communicate with patients, you will see that many are not," emphasizes Weiss, noting that physicians routinely use complex medical jargon that patients do not understand.

Illustrate the problem

To address this problem, Weiss suggests the NVS can be used to effectively demonstrate to physicians that patients in their own practice do not fully understand important health information given to them during office visits. This can be accomplished by administering the NVS to a sample of patients in the practice -- perhaps the first 100 who walk in the door, notes Weiss.

"Physicians are uniformly stunned to find out that as many as half their patients do not [fully grasp the information]," he stresses. The statistics make clear that every physician inevitably has patients with limited literacy skills. "So I think there is a consciousness-rais-

ing process that needs to happen first, then we need to work on physicians' communications style. But without raising their consciousness, they don't perceive the need to change their communication."

Once practitioners realize they need to communicate more effectively with at least some of their patients, there are a number of strategies they can employ. First, Weiss says it is not enough to ask a patient whether he understands the information you have explained, because patients routinely will answer this question affirmatively even when they do not grasp the information. A much better approach is to ask the patient how he will convey that information to his spouse when he gets home. "Then they [state] what they are going to say to their spouse, and you get a sense of whether they understood what you told them," says Weiss. "Frequently, you find that they didn't really get it at all."

Other effective communications strategies include talking slowly and clearly, encouraging patients to ask questions, and using pictures whenever possible as opposed to text. Additionally, Weiss emphasizes that practitioners should never assume that a patient understands.

"You can't tell by looking at people. Most people with the lowest literacy skills are white, native-born Americans. They are not African Americans or Hispanics or other ethnic minorities," he says. "In those

Figure 2: The Newest Vital Sign -- English

Nutrition Facts		ANSWER CORRECT?	
		YES	NO
Serving Size	1/2 cup		
Servings per container	4		
Amount per serving			
Calories 250	Fat Cal 120		
	%DV		
Total Fat 13g	20%		
Sat Fat 9g	40%		
Cholesterol 28mg	12%		
Sodium 55mg	2%		
Total Carbohydrate 30g	12%		
Dietary Fiber 2g			
Sugars 23g			
Protein 4g	8%		
* Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.			
Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.			
<small>Note: This single scenario is the final English version of the newest vital sign. The type size should be 14-point (as shown above) or larger. Patients are presented with the above scenario and asked the questions shown in Figure 1b.</small>			
READ TO SUBJECT: This information is on the back of a container of a pint of ice cream.			
QUESTIONS			
1. If you eat the entire container, how many calories will you eat?			
Answer <input type="checkbox"/> 1,000 is the only correct answer			
2. If you are allowed to eat 60 g of carbohydrates as a snack, how much ice cream could you have?			
Answer Any of the following is correct:			
<input type="checkbox"/> 1 cup (or any amount up to 1 cup)			
<input type="checkbox"/> Half the container			
Note: If patient answers "2 servings," ask "How much ice cream would that be if you were to measure it into a bowl?"			
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?			
Answer 33 is the only correct answer			
4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?			
Answer 10% is the only correct answer			
Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings.			
5. Is it safe for you to eat this ice cream?			
Answer <input type="checkbox"/> No			
6. (Ask only if the patient responds "no" to question 5): Why not?			
Answer Because it has peanut oil.			
Total Correct			

Source: Weiss B, Mays M, Martz W, et al. Quick Assessment of Literacy in Primary Care: The Newest Vital Sign, *Annals of Family Medicine* 2005; 3:514-522.

groups, the low literacy rate is higher, but most people with low literacy are white, so you should assume that any patient is a low-literacy patient."

Editor's note: Researchers are now investigating whether the NVS can be further refined so the instrument can be administered even more swiftly. Additionally, investigators are evaluating whether the tool can predict health outcomes or utilization patterns. Meanwhile, the NVS is being made available free-of-charge to

health care organizations and practitioners to use as they see fit. More information is available in the Nov/Dec issue of *Annals of Family Medicine* at www.annfammed.org.

Reference

1. Weiss B, Mays M, Martz W, et al. Quick Assessment of Literacy in Primary Care: The Newest Vital Sign. *Annals of Family Medicine* 2005; 3:514-522. ❖

Model pairs personal nurse with each participant

Pfizer and Humana join forces on new Medicare Health Support program

Almost lost in the media blitz surrounding the start of Medicare's new prescription drug benefit has been another potentially groundbreaking development: the rollout of Green Ribbon Health, the seventh of eight pilot programs CMS has tapped to test the applicability of offering a DM-style intervention to Medicare fee-for-service beneficiaries with diabetes and/or CHF. Green Ribbon Health, based in Tampa, FL, is actually a new company formed by health care giants Humana and Pfizer, with the idea of applying the best DM approaches and techniques that each firm has to offer to the 20,000 complex care recipients that have been identified by CMS to participate in the program.

Like the other Medicare Health Support programs, most of which began operations earlier in 2005, Green Ribbon Health has three years from its November 1, 2005 start date to prove that it can boost outcomes while remaining at least budget neutral, although the Secretary of Health can move to expand these programs if there is enough data to support such a move after just two years. Company administrators are hoping to succeed at this task by pairing each participant with a personal nurse who can help guide health care decision-making -- and by taking full advantage of existing community resources.

DM is put to the test

Medicare Health Support is CMS's first large-scale attempt to apply the principles of DM to traditional fee-for-service recipients. The demonstration project was authorized by the landmark Medicare Modernization Act in December of 2003, and it is recognized as a huge test for the DM industry, which is virtually assured of monumental growth if the eight pilot programs are largely successful.

At each pilot site, the costs and outcomes of the 20,000 participants identified for intervention are being tracked along with the costs and outcomes of a matched group of 10,000 Medicare recipients who are

serving as a control group. It's an attempt to transform Medicare from an agency that simply pays bills into one that improves quality and contains costs, according to **Barbara Hoffman**, director of Chronic Care Improvement Programs for CMS. "We know that chronic conditions drive disproportionate costs and take a toll on our beneficiaries and families," she says. "Ultimately, we are looking to demonstrate sustained quality and cost outcomes in programs that are acceptable to beneficiaries and their providers."

Under the criteria established by CMS, all of the pilot programs are offering self-care guidance and support to help beneficiaries follow their physicians' recommendations and manage their own health. Further, providers are all being held responsible for the outcomes of the entire intervention group -- not just those who voluntarily elect to participate. However, each site has developed its own infrastructure for accomplishing these goals, and the model established by Green Ribbon Health is based on establishing a relationship between each participant and a personal nurse -- an approach largely borrowed from Humana's personal nurse program.

"That personal nurse works at customizing each person's experience by first getting to know them, their values, their preferences, and their perspectives about life and health," explains **Jean Bisio**, CEO of Green Ribbon Health. "She or he coordinates with the recipient's doctor, a wide range of community resources, peer educators, social workers, pharmacists, and geriatric specialists."

Bisio emphasizes that this level of care is needed because of the complex nature of the target population. "Our average beneficiary saw 15 providers last year and is on 12 prescription medications. From that, you can obviously see the need for care coordination."

Relationship building

Typically, this relationship-building process begins with a phone call from the personal nurse to the recipient. "We give them information about the benefits of the program, let them know what we are or are not, and then they give their permission to participate in the program," explains **Kate Marcus**, RN, MS, CPHQ, a personal health coach with Green Ribbon

Health. "From there, we collect some initial information about their health status so that we have some baseline information on them -- because as the program goes on, we want to work with each of the participants on health promotion activities that are important to them, and we are going to collect data as we go along to show what improvements have been made."

The data-collection process is facilitated by Pfizer's InformaCare program, a web application that enables nurses to document every encounter with a recipient and track progress and outcomes over time. "We know that we are working with beneficiaries who have diabetes and/or CHF, but we also want to work on whatever is important to that beneficiary so that they can take care of that, and move on to take care of themselves," adds Marcus.

A nurse in the family?

This type of intervention can involve more than just purely health-related matters, stresses Bisio, noting the case of one recipient who could not focus on her diabetes because she didn't have the resources to provide a Thanksgiving dinner for her family. "The personal nurse immediately contacted one of Green Ribbon Health's community liaisons, and together they worked successfully to get a Thanksgiving dinner for this grandmother and her family. In addition, they got food vouchers for this woman so she could stock her pantry, and she was left with the promise of Christmas presents for her grandchildren over the holidays," she explains. "By helping to solve what was immediate for this individual, we have been able to build a trusting relationship with her, and she can now begin to focus on her own health, and work on specific actions to manage her diabetes and cardiac disease."

More commonly, the personal nurse uncovers problems or difficulties that a recipient may not have even raised with his or her physician. For example, Marcus notes, many diabetic patients do not understand how to use their glucose meters correctly, and so they are unable to accurately test their blood sugars. "We have social workers and community health workers who can go out and visit a participant in the home ... or we can ask them to call the nurse at their doctor's office," notes Marcus. "We have had a very good reception from the physicians' offices when we have the beneficiary go into the office and get some instruction on how to use their meter. They may not want to bother the physician, but this reinforces that relationship."

It is also not uncommon for the personal nurse to discover medication errors. For example, Marcus recalls the case of one recipient who was reviewing her list of medications with the nurse, and mentioned that she had been feeling light-headed. "At this point, the recipient realized that her physician

had made a change in her BP medication, and that she had been taking double the prescribed dose," notes Marcus. "So it is like having someone there to be a sounding board. Some people have said it is like having a nurse in the family because it is really having someone to advocate for participants when they are not sure what to do."

In-person visits

The personal nurses primarily work with the recipients via telephone. However, they have at their disposal field care managers, who are nurses or social workers and can make in-person visits when appropriate. "The personal nurses use some of the interviewing that they do to uncover patient needs. If someone is so hard of hearing that they cannot answer questions, we want to send someone into the home," notes Marcus. "And there are also triggers that the nurse listens for but are also actually calculated by the system, so that if someone has fallen in the last six months and there is some question about their cognitive ability or their ability to live independently, these are all triggers that will prompt the nurse to refer the person to a field care manager for a home visit."

Also part of the model are community health workers, non-professionals who work with the nurses and social workers to identify resources in the community, set up classes dealing with health promotion activities of interest to participants, and organize fitness-related activities such as walking clubs. Community health workers are also available to make home visits in cases where a nurse or social worker is not required.

A primary goal of the personal nurses and their colleagues in the model is to achieve sustained behavior change, according to **Jonathan Lord, MD**, Humana's chief innovation officer. "With the complexity of illness that these people are experiencing, they need to be making changes throughout their lives -- not just one time, but on an ongoing basis," he says, noting that skills such as motivational interviewing and relapse prevention are part of the nurses' core training. "They are helping people learn how to use the health care system the same way a personal trainer teaches people how to use a gym."

By mid-December, Green Ribbon Health had already engaged about one-third of the 20,000 participants identified for intervention, so the program is ahead of schedule, according to Bisio. There are at least two years to go before CMS will move to expand any of the pilot programs, but hopes are high that the experiment will prove worthwhile for both Medicare and its beneficiaries.

Editor's note: For more information about Green Ribbon Health, visit the organization's web address at www.greenribbonhealth.com. ♦

New report: Diabetes epidemic threatens progress on other fronts

There has been plenty of talk in recent years about the importance of putting more energy and health care dollars behind prevention, but that talk has failed to generate the kind of action that is needed to reduce or even manage the escalating burden of chronic disease in this country. That, at least, is the contention of a new report by the Yale School of Public Health in conjunction with the Institute for Alternative Futures. The report, which was commissioned by Princeton, NJ-based Novo Nordisk, issues a particularly stern warning about diabetes, contending that if current trends and policies continue, diabetes is likely to be the nation's number one killer within 20 years.

To prevent such predictions from becoming reality, the report, *Barriers to Chronic Disease Care in the United States of America: The Case of Diabetes and its Consequences*, suggests that what is urgently needed is a dramatic shift in focus toward promoting health, as opposed to just treating disease, and a concerted effort within the larger corporate sector to curtail the epidemic of obesity that is largely responsible for the burgeoning number of diabetes cases.

An escalating problem

The report's predictions regarding diabetes are actually based on a fairly modest set of observations and assumptions, according to the report's lead author, **Derek Yach**, MBChB, MPH, professor and head of the Division of Global Health at the Yale School of Public Health. "If you look at the trends in cardiovascular disease generally, we have seen a sustained decline, which is obviously very good news, compared to a fairly steady increase in terms of diabetes," he says. (See Figure 1.) "And when you model this through over time, you come to diabetes emerging or getting close to the number one cause of death."

This calculation presumes that the current relationship between obesity and diabetes remains the same, and that there are no significant changes in current levels of treatment. Adds Yach, "If there was a dramatically improved set of treatments on the table, that would, of course, change the figures somewhat, but we have to understand how badly that would be offset by the much higher incidence of diabetes that we are expecting."

In fact, if something is not done to check the growing prevalence of diabetes, the report argues, it could threaten the progress that has been made with regards to other chronic conditions, and especially

cardiovascular disease. To alter the course of this scenario, the report urges policy makers to address six systemic barriers to chronic disease care:

- the orientation of the health system toward acute care;
- a delivery system based primarily on acute, episodic physician visits;
- inadequate quality benchmarks and best practices for chronic disease care;
- under-funded and under-valued health services research;
- under-funded and under-valued health promotion and chronic disease prevention activities;
- insufficient incentives for prevention and long-term chronic disease management.

Unrealistic demands

One of the chief problems with the funding of most DM initiatives is the short-term thinking of both private and public-sector payers, emphasizes Yach. "To have recovery of costs within a year for chronic disease in a big population where it takes

Figure 1: Trends in Age-Standardized Death Rates for the Six Leading Causes of Death in the United States

	Death Rate		
	1970	2002	% Change
All Causes	1242.2	844.6	-32.0
Heart Disease	502.6	240.5	-52.1
Cancer	198.8	193.5	-2.7
Stroke	151.9	56.1	-63.1
COPD	21.4	43.4	102.8
Accidents	62.5	36.9	-41.0
Diabetes Mellitus	24.6	25.4	3.2

Data source: Jemal, A., Ward, E., Hao, Y., Thun, M. "Trends in the Leading Causes of Death in the United States, 1970-2002." *JAMA*. 294(10): 1255-1259. 2005.

Source: Reprinted from: *Barriers to Chronic Disease Care in the United States of America: The Case of Diabetes and its Consequences*, a report by Yale University Schools of Public Health and the Institute for Alternative Futures 2005.

Figure 2: The Most Common Combinations of Co-Morbid Conditions Ranked by Percentage

Rank	Disease Combination	Prevalence Estimate
1	Hypertension and Dyslipidemia	35.9 per 1,000
2	Anxiety and Depression	20.7 per 1,000
3	Diabetes, Hypertension, and Dyslipidemia	15.1 per 1,000
4	Osteoarthritis and Hypertension	8.7 per 1,000
5	Depression and Dyslipidemia	8.2 per 1,000
6	Osteoarthritis and Dyslipidemia	7.4 per 1,000
7	Diabetes and Hypertension	6.4 per 1,000
8	Diabetes, Heart Disease, Hypertension, and Dyslipidemia	6.1 per 1,000
9	Asthma and Depression	5.9 per 1,000
10	Diabetes and Dyslipidemia	5.8 per 1,000

Data provided by Yankelovich, Inc. from Preventative Health Behaviors Survey, Aug. 2005.

Source: Reprinted from: *Barriers to Chronic Disease Care in the United States of America: The Case of Diabetes and its Consequences*, a report by Yale University Schools of Public Health and the Institute for Alternative Futures 2005.

real time to bring about behavior change, and then for behavior change to reduce risk, and then for reduced risk to reduce disease -- that is not in sync with the basic epidemiology and biology of what we know about disease. It is placing unrealistic demands on what we know about public health," he says. "These things take years, and even decades to improve."

In terms of adopting best practices and benchmarks, Yach points out that the continuing focus on single-disease treatment guidelines ignores the reality that people over the age of 60 are likely to have more than one chronic disease. (See Figure 2 on page 10.) "The more drugs you [prescribe] for a person, the lower the adherence rate, the higher the probability for complications, and the higher the probability of untoward interactions occurring between the drugs," he says. "So, our call is for fewer disease-specific guidelines, and more of an integrated approach to the management of the patient."

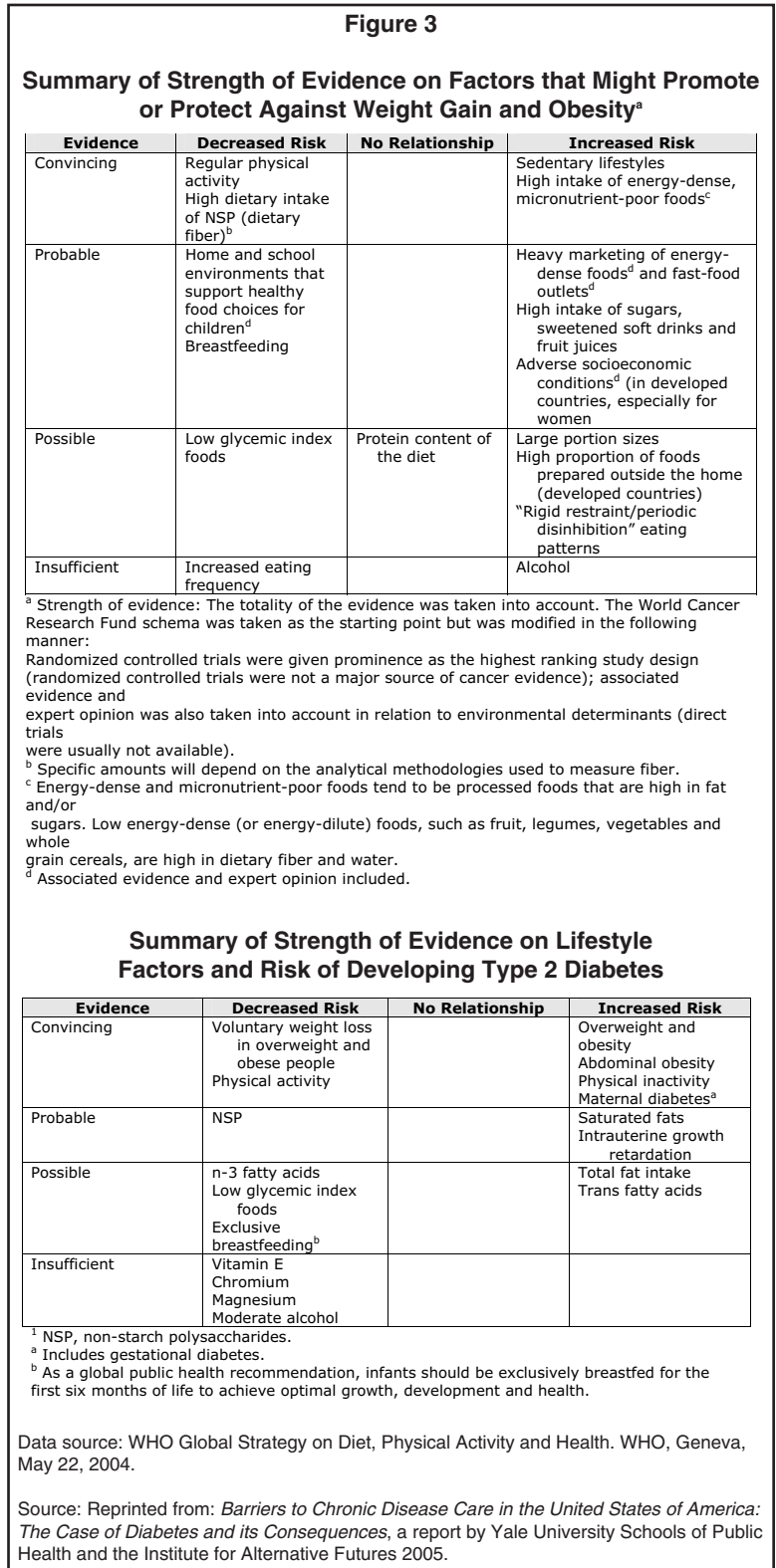
Wellness programs deliver

On the positive side, Yach notes that corporate America is beginning to recognize the importance of health promotion to its bottom line, and the evidence in favor of wellness programs is getting stronger. "It shows that virtually for every dollar that is invested in these new health and wellness programs, you can expect a return of three to four dollars in gains," he stresses. "That is a pretty good ROI when you measure it in economic terms, and I think we have sufficient knowledge now to do a lot, but the one area where there isn't sufficient knowledge of what will truly work is around obesity."

Unfortunately, while progress has been made in controlling cholesterol levels, blood pressure, smoking prevalence, and even stress, Yach points out there are no large-scale examples in the workplace or in the community of obesity levels going down. And obesity is a key diabetes trigger. (See Figure 3 on page 11.) "Nobody has got what they could really call the best practices to apply across the working environment"

But Yach is nonetheless optimistic that market forces outside of the healthcare industry are moving in the right direction. "Consumers are starting to demand different types of food and better access to physical activity, we are seeing smoking rates come down in all but the poorest and most marginalized groups, and companies are starting to respond," he explains. "So it's paradoxical, but I would imagine that over the next few years the prevention and wellness sector will expand fairly rapidly where we may see very little change in the current health system."

Editor's note: The report, *Barriers to Chronic Disease Care in the United States of America: The Case of Diabetes and its Consequences*, can be accessed via the Novo Nordisk web site at www.novonordisk-us.com/documents/home_page/document/index.asp. It was commissioned by Novo Nordisk as the initial step in its National Changing Diabetes Program, an initiative aimed at stimulating system-wide change. ♦



2006 Disease Management Directory & Guidebook Now Available

NHI has just released the all-new 2006 edition of the Disease Management Directory & Guidebook. For the past eight years, the disease management industry has relied on one source for the most current, detailed information available on DM trends, programs, vendors, resources, strategies, and outcomes. This year is no exception with the completely updated 2006 *Disease Management Directory & Guidebook*. It's our most comprehensive edition yet! Inside its 500+ pages you'll discover:

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